

Discrepancy Between Stent Deployment and Balloon Size Used Assessed by Intravascular Ultrasound

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Objectives: This study was designed to assess the discrepancy in stent deployment seen on intravascular ultrasound and its relation to the balloon size selected for stent delivery.

Design: Prospective study.

Materials and Methods: The study group comprised 27 patients treated using a stent ($n=18$) or stent-graft combination ($n=9$). Following angiographically optimal stent deployment ($<10\%$ residual stenosis) intravascular ultrasound was used to compare the smallest intra-stent lumen area with measurements at both stent edges and the lumen area of the proximal and distal reference sites.

Results: In 14 of the 27 stents the intra-stent dimension was the same as the dimension of the stent edge (difference $\leq \pm 10\%$). Of the remaining stents the intra-stent dimension was smaller (difference $>10\%$) than the proximal stent edge in seven stents (range 11–39%), smaller than the distal stent edge in three stents (range 11–20%) and smaller than both stent edges in three stents (range 12–37%). Both in patients treated with a stent or stent-graft combination, the resulting smallest intra-stent lumen area was smaller than the balloon size used (mean difference 32% and 42%, respectively) and smaller than the mean lumen area of the reference sites (mean difference 25% and 23%, respectively).

Conclusion: This intravascular ultrasound study shows a discrepancy between intra-stent lumen area, the area of the stent edges and the balloon size used.

Key Words: Intravascular ultrasound; Stent; Diameter; Stenosis; Aneurysm.

Introduction

To improve the immediate and long-term results of vascular interventions, stent deployment is used in various vascular sites.^{1–3} In the coronary arteries intravascular ultrasound has revealed that stents may be incompletely deployed despite optimal angiographic results, and consequently interventional strategies have been modified.^{2,4–8} The present study describes stent deployment in non-coronary sites assessed with intravascular ultrasound, and examines the relationship to the balloon size used.

Subjects and Methods

The study included 27 patients (17 men and 10 women, median age 65 (range 36–86) years)) successfully

treated with a stent ($n=18$) or a combined stent-graft ($n=9$) placement. Success was defined as a residual diameter stenosis $<10\%$ with a smooth lumen of the stented segment and without an endoleak to the aneurysm. Balloon-expandable stents were used (Palmaz; Johnson and Johnson, Interventional Systems, NJ, U.S.A.). The subclavian artery ($n=4$), the common iliac artery ($n=10$), and the superficial femoral artery ($n=13$) were treated. Patients were scheduled for intervention based on angiographic data (diameter stenosis $>50\%$ or aneurysm). Indications for stenting were suboptimal balloon angioplasty ($n=15$), elective ($n=1$), and a dissection larger than the initial lesion ($n=2$). Stent-graft combinations (Palmaz stent + ePTFE graft) were used to treat peripheral arterial aneurysm ($n=6$) and false aneurysms at graft anastomoses ($n=3$).

Dilatations were performed with a compliant balloon (OPTA, Cordis, Europe BV). The size of the balloon and stent were selected on the basis of pre-deployment intravascular ultrasound. For this purpose the diameter of the original vessel wall (media-to-media) at the location of the diseased stenotic segment

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was used, or the diameter of the normal lumen where the stent-graft would be anchored. Inflation time and pressure were left to the discretion of the interventionalist based on fluoroscopy and angiography.

Intravascular ultrasound

Intravascular ultrasound studies were performed with a mechanical system containing a rotating single ultrasound element (30 MHz; Endosonics, Rijswijk, The Netherlands) using a 4.3-French flexible catheter ("Princeps"). Before and immediately after intervention the ultrasound catheter was advanced distally and cross-sections were obtained during pull-back of the catheter. The resulting images together with their unique frame number were displayed on a monitor via a video-scanned memory and stored on an S-VHS video system. Cross-sectional area measurements were performed off-line using a computer-based analysis system.⁹ Measurements included: (1) *before intervention* assessment of reference vessel area (bounded by the media) in those cross-sections used to determine balloon size and stent size; and (2) *after intervention* assessment of the area at the two stent edges (entry and exit), the smallest area within each stent (intra-stent dimension), and the mean lumen area of the proximal and distal reference segment. The reference segments were, by definition, within 1–2 cm of the stented segment showing the largest lumen area without side-branches. Stent deployment was reviewed for:

- (1) Comparison between the lumen area measured at the deployed stent edges and within each stent. The difference between stent area measured at the edges and within the stent (smallest area) was calculated and expressed as a percentage of the smallest area within the stent. A relative stent area at the stent edge of >110% indicates a larger edge; a relative stent dimension at the edge of 90–110% indicates no difference. The cut-off point of 10% was used to correct for intraobserver differences in measurements.
- (2) Comparison between balloon area and vessel area in those ultrasound cross-sections obtained before intervention on which the size of the balloon used was based. Balloon area was derived from specifications provided by the manufacturer.
- (3) Comparison between balloon area used and the smallest stent area.
- (4) Comparison between the smallest stent area and the reference lumen area (mean of proximal and distal reference area) seen after intervention. A distinction was made between data derived from

stents and stent-grafts, as well as between data derived from the subclavian, common iliac and femoral arteries.

- (5) Apposition of the stent to the vessel wall (without protrusion of the struts within the lumen).
- (6) Stent symmetry at the stent edges and within the stent, which was calculated by dividing minimum and maximum diameter.

To assess intraobserver variability between lumen, vessel and stent areas, the cross-sections selected were analysed blind by the same observer with an interval of 2 months.

Statistical analysis

All values are given as mean \pm standard deviation (s.d.). Differences in area measurement were examined with the Student's *t*-test. In order to describe intraobserver agreement the area, mean \pm s.d. of the paired differences between the measurements were given. The Student's *t*-test was used to determine whether there were systematic intraobserver differences. The degree of intraobserver variation is presented with a coefficient of variation defined as the s.d. of the paired difference divided by the mean of the absolute value. A *p*-value <0.05 was considered statistically significant.

Results

The mean length of stents used was 3.0 cm (range 1.0–4.5 cm); the mean pressure to implant the stent against the arterial wall was 11 ± 1 atm.

All intravascular ultrasound studies were completed successfully. Table 1 summarises the quantitative data obtained.

Table 1. Balloon size and intravascular ultrasound measurements (mean \pm s.d.) through the implanted stent and adjacent vessel segments in the study population.

		Stenosis (<i>n</i> = 18) mm ²	Aneurysm (<i>n</i> = 9) mm ²
Balloon size		46.8 \pm 26.4	93.1 \pm 59.6
Before intervention			
Reference vessel area		53.7 \pm 31.9	84.4 \pm 51.3
After intervention			
Stent area	smallest	32.0 \pm 21.4	54.2 \pm 35.9
	largest	38.9 \pm 24.2	72.4 \pm 44.3
Reference lumen area	mean	42.8 \pm 29.6	70.8 \pm 48.3

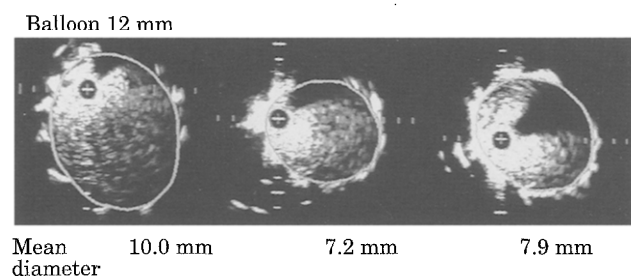


Fig. 1. Intravascular ultrasound cross-sections of the iliac artery after stent-graft placement for an aneurysm using a 12 mm balloon. Diameters of the proximal stent edge (A), intra-stent (B) and distal stent edge (C) are smaller than the balloon diameter used. + = catheter; calibration 1 mm.

- (1) Comparing the intra-stent lumen area and the lumen area of the stent edges individually in each stent, it was found that in 14 stents the areas were in the same order. In the remaining 13 stents either the area of the proximal stent edge ($n=7$; range 11–39%) or of the distal stent edge ($n=3$; range 11–20%) was larger than both the intra-stent area and opposite stent edge area (Fig. 1). In three stents the intra-stent area was smaller than the area of both stent edges (range 12–37%).
- (2) The balloon size selected in patients treated for a stenosis was smaller (13%) than the reference vessel area seen on ultrasound before intervention. In patients treated for an aneurysm the balloon size selected was larger (10%) than the reference vessel area seen on ultrasound.
- (3) The balloon size used exceeded the resulting intra-stent lumen area. Mean difference between balloon size and smallest intra-stent area was 32% for patients treated for a stenosis and 42% for patients treated for an aneurysm. The difference between the balloon size and smallest intra-stent area was significant for the common iliac (44%) and superficial femoral artery (37%), but not for the subclavian artery (11%) (Fig. 2).
- (4) Comparing the smallest intra-stent area and the lumen area of the reference segment, a mean difference of 25% was seen for patients treated with a stent, and 23% for patients treated with a combined stent-graft. Individually, the difference between smallest intra-stent area and reference lumen area was less than 10% in seven patients; between 10% and 20% in three patients and between 20% and 56% in 17 patients.
- (5) Complete stent apposition with the struts touching the arterial wall was seen in all patients.
- (6) Data on the symmetry index indicate well deployed circular stents: an index of ≥ 0.7 was found in 100% of the stents, and an index of ≥ 0.8 was found in 95% of the stents, respectively.

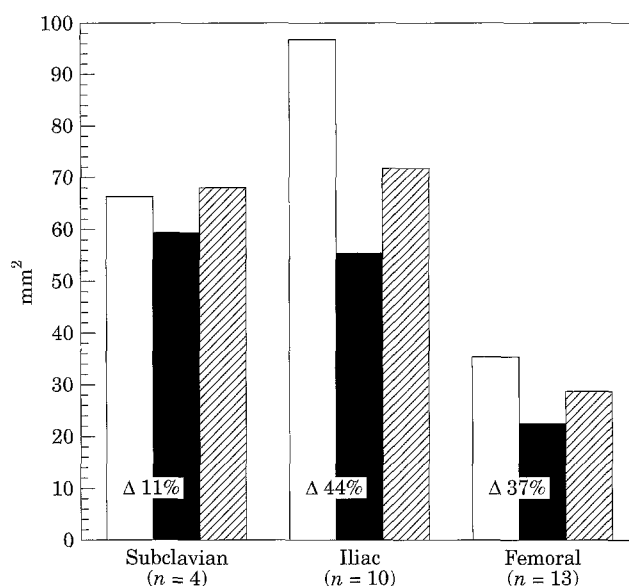


Fig. 2. Comparison between balloon size and stent areas measured with intravascular ultrasound. (□) Balloon size; (■) smallest stent; (▨) largest stent; (Δ) difference between balloon size and smallest stent area.

Of the intraobserver differences, none were statistically significant. The coefficient of variation of the vessel area assessed before intervention was 5%; for lumen and stent area assessed after intervention it was 7% and 6%, respectively.

Discussion

Endovascular treatment offers a minimally invasive therapy that is effective in most circulatory beds for an increasing array of pathology.¹⁰ The use of stent and stent-graft combinations to improve long-term patency of endovascular interventions is being investigated.¹⁰ Because angiography alone is insufficient to adequately monitor endovascular procedures, the comprehensive insight into vessel and stent geometry provided by intravascular ultrasound has played an important role in developing the concept of optimised stent deployment.¹¹ Despite good angiographic appearance the use of intravascular ultrasound in coronary arteries has resulted in a significant increase in intra-stent dimensions.^{2–4} Dilatation with low-compliant high-pressure oversized balloon has been advocated.^{5–8}

The present observational intravascular ultrasound study compared the balloon size used with the immediate outcome following stent or stent-graft implantation. The results show that well-apposed stents can vary in lumen dimensions despite the use of

adequately sized balloons. As expected, a good agreement was found between balloon size used and the reference vessel area seen prior to intervention. Irrespective of treated pathology, we found that in 14 of 27 stents a uniform expansion of the stent was achieved; a funnel-like shape was observed in 10 stents, while in three stents both stent edges were larger than the dimension seen within the stent. Moreover, a discrepancy was observed between balloon area and resulting stent area in patients treated for both a stenosis (difference 32%) and for an aneurysm (difference 42%). If, however, diameters were used, the difference between balloon and stent was 18% in patients treated with a stent and 23% in patients treated with a stent-graft combination. These observations concur with others reporting that the balloon diameter used for coronary artery application is larger than the resulting intra-stent diameter (difference 9–25%).^{3,4,6–8} Inadequate stent expansion may be caused by a balloon that is too small for the artery, by compression of the stent by the plaque,³ or by plaque resistance.⁸ Because discrepancy in stent expansion in the present study occurred in patients treated for both stenosis and aneurysm, we postulate that inability to expand the stent to a diameter equal to the balloon diameter is due to either the type of balloon used or the nature of the stent. It is noteworthy that in another study we found a similar under-expansion of the stent using a non-compliant balloon (Powerflex, Cordis Europe BV) (unpublished observations). This suggests that the balloon type used may not influence the outcome of stent deployment. It should be mentioned that, in the present study, the angiographic diameter stenosis (<10%) can not be compared with the area stenosis shown by intravascular ultrasound. If ultrasound diameter stenosis for stent and stent-graft combination was calculated, data (12% and 11%, respectively) were in the same order as the angiographic data. The individual differences seen between intra-stent diameter and reference lumen diameter were, however, indicative for a residual stenosis of >10% in 17 patients (between 10–20% stenosis in 11 patients and between 20–33% in six patients). The significance of this finding for clinical outcome is, however, not addressed in this study.

It is noteworthy that only stents in the subclavian artery reached the dimensions of the balloon size used. We assume this to be due to the oblique position of the ultrasound catheter tip within the arterial wall lumen, as such a position results in an elliptic cross-sectional image in which the lumen area appears to be larger than the actual lumen area. This assumption is supported by the finding that the mean minimal

intra-stent diameter seen within the subclavian artery stent (7.8 mm) was 13% smaller than the balloon diameter (9 mm).

Finally, it should be noted that for the present study the nominal size of the balloon was used. However, if its diameter was corrected for the pressure used, the mean expected balloon size increased 11%. This implies an even greater discrepancy between the balloon size used and the resulting intra-stent dimensions.

Limitation

This study was not designed as an outcome study to test whether these criteria predict clinical results after stent insertion. The study compares the ultrasonically assessed reference vessel area and stent area on the one hand, and the manufacturer's specified balloon diameters on the other. The balloon diameter specified by the manufacturer is determined under *in vitro* conditions. Both vessel wall and obstructing plaque, as well as the stent itself, may influence balloon expansion.⁹

Conclusion

This intravascular ultrasound study shows a discrepancy between the intra-stent lumen dimensions, the dimension of the stent edges and the balloon size used both in patients treated for a stenosis or an aneurysm. This discrepancy is not seen angiographically. Selection of larger balloon size and/or higher pressures than currently used might be warranted in future clinical applications.

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